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For Section 2(E) Case File

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Re: Support document control number
29070000471.

E#2



Andrea V. Malinowski
Corporate Counsel

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06 NOV -9 AM 11:17

November 8, 2006

VIA FEDERAL EXPRESS

TSCA Document Processing Center (7407M)
EPA East - Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, D.C. 20004-3302
Phone: 202-564-8940

**CONFIDENTIAL BUSINESS
INFORMATION**

**~~TSCA CONFIDENTIAL
BUSINESS INFORMATION
- DOES NOT CONTAIN NATIONAL
SECURITY INFORMATION (E.O. 12065)~~**

Re: **DuPont Submission Nos. 1-092 to 1-098**
Test formulations: Described in the attached Index of Reports
CD Submission (CBI version)

Dear Section 8(e) Coordinator:

On July 12, 2006, DuPont submitted a paper copy set of recently reviewed acute inhalation screening studies which were identified by the above-referenced DuPont submission numbers and which contained Confidential Business Information (CBI). With this submission, DuPont is providing a CD (CBI version) containing reports for studies identified as DuPont submission numbers 1-092 to 1-098 and also containing a copy of this transmittal letter, which includes has an Index of Reports attached to it. The public version of these reports, along with a CD containing those studies, is being submitted (with a separate transmittal letter) to EPA.

Please contact me directly if you have any questions or require further clarification.

Very truly yours,

Contain NO CBI

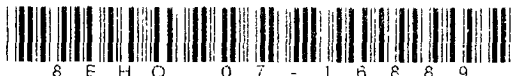
Andrea V. Malinowski

Attachment: Index of Reports 1-092 to 1-098 (2 pages)

Enclosure

- 1 CD labeled Submission Nos. 1-092 to 1-098 (CBI version)

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SECURITY INFORMATION (E.O. 12065)~~**



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Attachment
Index of Reports 1-092 to 1-098

DUPONT SUBMISSION NUMBER	REPORT NUMBER	NO. OF PAGES (W/ COVER SHEET)	TEST SUBSTANCE
1-092	54-83	8	4 materials tested: (1) douglas fir, (2) tetrafluoroethylene, (3) poly(methyl acrylate/acrylonitrile/sodium p-styrene sulfonate [Orlon® type 42 acrylic fiber], and (4) tetrafluoroethylene/hexafluoropropylene copolymer
1-093	256-88	14	2-pentanol, 2,4,4-trimethyl-3-nitroso-, nitrate; CAS number 65152-04-7
1-094	403-83	8	Telomeric acid fluoride, described as 3,5,7,9,11-pentaoxadodecanoyl fluoride, 2,2,4,4,6,6,8,8,10,10,12,12,12,-tridecafluoro-; ALC studies referenced in this study were submitted under the CAP
1-095	11220	12	Boron, triphenyl(pyridine)-,(T-4); CAS number 971-66-4
1-096	38-93	12	88-90% sodium alkylnaphthalene sulfonate, 7-9% sodium sulfate, 2-3% water
1-097		1	Removed
1-098	128-81	4	55% (E)-2,3,dichloro-2-buten-1-01 (CAS number 36555-44-9) and 40% (Z)-2,3,dichloro-2-buten-1-01 (CAS number 60838-32-6) and 5% unknowns

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Acute Inhalation Studies – 1st Submission
Extreme/High Classification

July 12, 2006

E #2

DuPont Submission No.

1-093

Report No.

256-88

1-093

E #2

FOR DU PONT USE ONLY

Du Pont HLR 256-88
Revised Page

Contains TSCA CBI

Study Title

Inhalation Approximate Lethal Concentration (ALC) of
Diisobutylene Nitrosate (DIBN)

Contains TSCA CBI

Author

Rudolph Valentine

Original Report Completed: April 15, 1988

Revision No. 1 May 1, 1997

Performing Laboratory

E. I. du Pont de Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
Elkton Road, P. O. Box 50
Newark, Delaware 19714

Medical Research No.

8209-001

Laboratory Project ID

Haskell Laboratory Report No. 256-88

Contains TSCA CBI

GENERAL INFORMATION

Material Tested:

[2-Pentanol, 2,4,4-trimethyl-3-nitroso-, nitrate]

Medical Research No.:

8209-001

Haskell No.:

16.970

Physical Form:

Blue-green liquid.

Composition:

[Approximately 44% diisobutylene nitrosate
Approximately 56% diisobutylene]

Contaminants:

[Several percent of C4 and C12 hydrocarbons are present in the product.]

Other Codes:

41310426

CAS Registry Number:

[65152-04-7]

Synonyms:

- [
• Diisobutylene nitrosate
• DIBN
]

Stability:

The test material was assumed to be stable throughout the exposure phase of the study.

Sponsor:

DuPont Dow Elastomers L. L. C.
E. I. du Pont de Nemours and Company
Wilmington, Delaware

GENERAL INFORMATION (Cont'd)

Material Submitted By: P. A. Johnson
Polymer Products Department
E. I. du Pont de Nemours and Company
Louisville, Kentucky

In-Life Phase

Initiated - Completed: 3/28/88 - 4/11/88

Notebook: E-56694, pp. 1-91.

There are 13 pages in this report.

Inhalation Approximate Lethal Concentration (ALC) of DIBN

SUMMARY

Groups of 6 male Crl:CD¹BR rats were exposed for a single, 4-hour period to atmospheres of DIBN in air. Test atmospheres were generated by atomizing the liquid test material with a nebulizer. The atmospheric concentration of aerosol was measured by gravimetric analysis and the concentration of 2,4,4-trimethylpentene, the major component of DIBN, was determined by gas chromatography. After exposure, rats were observed for clinical signs of toxicity during a 14 day recovery period.

Under the conditions of this study, the ALC for DIBN is 0.43 mg/L of aerosol combined with 3.7 mg/L of 2,4,4-trimethylpentene vapor. Deaths occurred during exposure at concentrations of 0.43 mg/L of aerosol combined with 3.7 mg/L of 2,4,4-trimethylpentene vapor or greater. Clinical signs of toxicity were limited to ocular, oral or nasal discharges and wet perineum during exposure and slight to severe weight losses, urine-stained perineum and diarrhea during the recovery period. Although the aerosol alone was considered to be moderately toxic (ALC between 0.2 and 0.8 mg/L of aerosol), based on the total atmospheric concentration of aerosol and 2,4,4-trimethylpentene vapor, the ALC for the mixture was 4.1 mg/L.

Work by:

R. T. Turner

R. T. Turner
Technician

Study Director:

R. Valentine

Rudolph Valentine, Ph.D.
Senior Research Toxicologist
Inhalation & Cellular Toxicology

5/1/97

Date

QUALITY ASSURANCE DOCUMENTATION

STUDY: MR 8209-001
H# 16.970

Inhalation Approximate Lethal Concentration (ALC)
of Diisobutylene Nitrosate (DIBN)

Because short-term studies are numerous and routine in nature, representative studies from this test type were audited quarterly to ensure the studies are designed and conducted in compliance with the Good Laboratory Practice Standards.

Revision No. 1 was reviewed on 4/7/97 for consistency with the original report and the reasons for revision.

Reported by: Kimberly B. Brubner for KLR 5/1/17
Kathleen L. Reed Date
Senior Quality Assurance Auditor

INTRODUCTION

The purpose of this study was to determine a 4-hour inhalation ALC for DIBN in male rats. The ALC was defined as the lowest atmospheric concentration tested that caused the death of 1 or more rats either on the day of exposure or within 14 days post exposure. Except as documented in the study records, this study was conducted according to the applicable Good Laboratory Practice Regulations.

MATERIALS AND METHODS

A. Animal Husbandry

Young adult male Crl:CD¹ BR rats were received from Charles River Breeding Laboratories, Kingston, New York. Each rat was assigned a unique 6-digit identification number which corresponded to a numbered card affixed to the cage. Rats were quarantined for approximately one week prior to testing, and were weighed and observed three times during the quarantine period. During the test, rats were housed in pairs in 8" x 14" x 8" suspended, stainless steel, wire-mesh cages. The rat assigned the lower number in each cage was identified by a slash in the right ear. Prior to exposure, rats' tails and cage cards were color-coded with water-insoluble markers so that individual rats could be identified after exposure. Except during exposure, Purina Certified Rodent Chow[®] #5002 and water were available ad libitum.

Animal rooms were maintained on a timer-controlled, 12 hour/12 hour light/dark cycle. Environmental conditions of the rooms were targeted for a temperature of 23 ± 2°C and relative humidity of 50 ± 10%. Excursions outside these ranges were judged to have been of insufficient magnitude and/or duration to have adversely affected the validity of the study.

B. Exposure Protocol

Groups of 6 rats, 8-9 weeks old and weighing between 237 and 325 grams, were restrained in perforated, stainless steel cylinders with conical nose pieces. The restrainers were inserted into a face plate on the exposure chamber such that only the nose of each rat protruded into the chamber. Each group was exposed nose-only for a single, 4-hour period to aerosol/vapor atmospheres of DIBN in air. Rats were weighed prior to exposure, and were observed for clinical signs of toxicity during exposure. Surviving rats were weighed and observed daily for 14 days post exposure; weekends and holidays excluded except when warranted by the rats' condition.

C. Atmosphere Generation

Test atmospheres of DIBN were generated by atomization. The test material was metered into a Spraying Systems nebulizer with a Harvard Model 975 Compact Infusion Pump. Air introduced at the nebulizer (approximately 14 L/min) atomized the test material and swept the resulting aerosol/vapor mixture into a 1-L glass cyclonic elutriator. The cyclone removed the larger particles by impaction and allowed the smaller particles to enter the 38-L cylindrical, glass exposure chamber. Test atmospheres were dispersed with a baffle within the chamber to promote uniform distribution. Chamber atmospheres were exhausted through a dry-ice cold trap and a MSA cartridge filter prior to discharge into a fume hood.

D. Analytical

Two analytical methods were used to determine the atmospheric concentration of the test material. A gas chromatographic method was developed to determine the atmospheric concentration of 2,4,4-trimethylpentene, the major component of DIBN. In addition, a gravimetric method was used to estimate the concentration of aerosol. Chamber samples were collected with a sampling train consisting of a 25 mm filter cassette and/or tandem impingers containing either acetone or methylene chloride as a trapping solvent.

Gravimetric Analysis

The atmospheric concentration of aerosol was determined at approximately 30-minute intervals by gravimetric analysis during most exposures. Known volumes of chamber atmospheres were drawn through preweighed, Gelman glass fiber (type A/E) filters. Filters were weighed on a Cahn Model 28 Automatic Electrobalance. The atmospheric concentration of aerosol was calculated from the difference in the pre- and post-sampling filter weights.

For 3 exposures, each filter was weighed immediately after sampling and then placed in 5 mL of acetone or methylene chloride. Aliquots of the resulting solutions were analyzed by gas chromatography as described below. For 1 exposure, each filter was weighed immediately after sampling; every other filter was then dried in a desiccator and reweighed, and the remaining filters were placed in 5 mL of methylene chloride or acetone. Aliquots of the resulting solutions were chromatographed as described below to estimate the amount of 2,4,4-trimethylpentene removed by filtration.

Chromatographic Analysis

The atmospheric concentration of 2,4,4-trimethylpentene was monitored at approximately 30-minute intervals during each exposure. Known volumes of chamber atmospheres were drawn through tandem glass midjet impingers containing either acetone or methylene chloride as a trapping solvent. The impingers were inserted in a sampling train downstream from the filter assembly and were used to collect 2,4,4-trimethylpentene vapor that passed through the filter. The resulting solutions were analyzed by gas chromatography.

Impinger or filter samples were analyzed with a Hewlett Packard Model 5710A gas chromatograph equipped with a flame ionization detector. Samples were chromatographed isothermally at 95°C on a 6' x 1/4" o.d. glass column packed with 3% SE-30 on 80/100 mesh Chromasorb W HP. The atmospheric concentration of 2,4,4-trimethylpentene was determined by comparing the detector response of samples with standard curves. Standards were prepared by quantitatively diluting 2,4,4-trimethylpentene (Aldrich Chemical Co., 99% pure) in methylene chloride.

Particle size (mass median aerodynamic diameter and percent less than 10 μ m) was determined with a Sierra Series 210 cascade impactor during most exposures. During each exposure, chamber temperature was measured with a mercury thermometer, relative humidity was measured with a Bendix Model 566 psychrometer, and chamber oxygen concentration was measured with a Biosystems Model 3100R oxygen analyzer.

E. Records Retention

All raw data and the final report will be stored in the archives of Haskell Laboratory for Toxicology and Industrial Medicine, Newark, Delaware, or at Iron Mountain (formerly the Du Pont Records Management Center), E. I. du Pont de Nemours and Company, Wilmington, Delaware.

RESULTS

A. Exposure Conditions and Associated Mortality

Aerosols of DIBN were readily observed during the exposures. Chamber temperature ranged from 23-24°C, relative humidity varied from 52-65%, and chamber oxygen concentration was 21.0%. Atmospheric aerosol and 2,4,4-trimethylpentene concentrations, and rat mortality data for each exposure are summarized in the following tables.

Characterization of DIBN Atmospheres
and Rat Mortality

Aerosol Concentration (mg/L) ^a				% Particles < 10 um AD ^b	MMD ^c (um)	Mortality deaths/# exposed)
Mean	S.D.	Range	n			
NM	NM	NM	NM	92	2.1	0/6
0.18	0.048	0.14 - 0.25	7	98	1.9	0/6
0.43	0.014	0.41 - 0.45	8	98	2.2	2/6
0.82	0.085	0.76 - 0.88	2	NM	NM	6/6
1.3	0.071	1.2 - 1.3	2	NM	NM	6/6

NM = Not Measured

^aValues shown represent the mean, standard deviation (S.D.), range and number of observations (n) for each exposure. Aerosol concentrations were based on wet filter weights. Due to the small amount of 2,4,4-trimethylpentene present on the filters (less than 2% of the total atmospheric concentration of 2,4,4-trimethylpentene was found on the filter samples), it was assumed that the filter weight gain was due to diisobutylene nitrosate. Approximately 11% of the sample mass remained on the filters after desiccation.

^bPercent by weight of particles with aerodynamic diameter (AD) less than 10 um.

^cMass median aerodynamic diameter.

Atmospheric Concentrations of 2,4,4-Trimethylpentene^a

2,4,4-Trimethylpentene Concentration ^b (mg/L)				
Aerosol Concentration	Mean	S.D.	Range	n
NM	1.6	0.11	1.5 - 1.7	4
0.18 mg/L	2.4	0.27	2.1 - 2.8	8
0.43 mg/L	3.7	0.12	3.5 - 3.9	8
0.82 mg/L	7.5	0.76	7.0 - 8.0	2
1.3 mg/L	11	0.58	11 - 12	2

NM = Not Measured

^a Data based on chromatographic analysis of impinger and filter samples.

^b Values shown represent the mean, standard deviation (S.D.), range and number of samples (n) for each exposure.

B. Clinical Observations

Deaths occurred during exposure at aerosol concentrations of 0.43 mg/L or greater. Upon release from the restrainers at the end of exposure, most surviving rats exhibited red nasal and ocular discharges; in addition, rats from the 0.18 mg/L groups had brown oral discharge and rats from the 0.43 mg/L group had wet perineum.

Clinical signs of toxicity in some rats during the recovery period were limited to diarrhea or brown-discolored fur, and urine-stained perineum. All clinical signs had resolved by day 3 post exposure. Most surviving rats from all groups exhibited slight to severe (up to 14% of initial body weight) weight loss within 24 hours of exposure. Rats began to regain weight 2 days post exposure.

DISCUSSION AND CONCLUSION

Under the conditions of this study, the ALC for DIBN is 0.43 mg/L of aerosol (assumed to represent diisobutylene nitrosate) combined with 3.7 mg/L of 2,4,4-trimethylpentene vapor. Although the aerosol alone was considered to be moderately toxic (ALC between 0.2 and 0.8 mg/L of aerosol), based on the total atmospheric concentration of aerosol and 2,4,4-trimethylpentene vapor, the ALC for the mixture was 4.1 mg/L.

¹ Calculation described in Sierra Instruments, Inc., Bulletin 7-79-219IM. Instruction Manual: Series 210 Ambient Cascade Impactors and Cyclone Preseparators.

Inhalation Approximate Lethal Concentration (ALC) of Diisobutylene Nitrosate (DIBN)

Reason for Revision No: 1

An electronic file of this report could not be found. For this reason, a copy of the original report was electronically scanned into a file.

Changes:

- Page 1 The title page was changed to reflect the revision.
"Inc." was removed from the Company name on Page 1 and throughout the report.
- Page 2 General Information
The sponsor is currently DuPont Dow Elastomers L. L. C.
Composition - From: [Approximately 20% diisobutylene nitrosate
Approximately 80% diisobutylene]
To: [Approximately 44% diisobutylene nitrosate
Approximately 56% diisobutylene]
- Page 3 General Information (cont'd)
The statement, "There are 10 pages in this report" was changed to reflect the revised page count.
A statement addressing distribution of the revised report was added.
- Page 4 Summary/Signatures
Summary: Second paragraph, second sentence
From: "Deaths occurred during exposure at concentration of 0.82 mg/L of aerosol combined with 7.5 mg/L of 2,4,4-trimethylpentene vapor, or greater."
To: "Deaths occurred during exposure at concentrations of 0.43 mg/L of aerosol combined with 3.7 mg/L of 2,4,4-trimethylpentene vapor or greater."
second paragraph, last sentence
From: Based on the total atmospheric concentration of aerosol and 2,4,4-trimethylpentene vapor, DIBN is considered to have very low toxicity on an acute inhalation basis.
To: Although the aerosol alone was considered to be moderately toxic (ALC between 0.2 and 0.8 mg/L of aerosol), based on the total atmospheric concentration of aerosol and 2,4,4-trimethylpentene vapor, the ALC for the mixture was 4.1 mg/L.

R. Valentine's current title was included.

The Acute and Developmental Toxicology Division is now Inhalation and Cellular Toxicology.

The reference to file "RV:smk:87.10" was deleted since this file no longer exists.

Page 5 Quality Assurance Documentation: Changed to include the audit of the revised report.

Page 8 Records Retention: The name of the current records retention center was added.

Page 10 Discussion and Conclusion, last sentence:

From: Based on the combined atmospheric concentrations of aerosol and 2,4,4-trimethylpentene vapor, DIBN is considered to have very low toxicity on an acute inhalation basis (ALC greater than 2 mg/L).

To: Although the aerosol alone was considered to be moderately toxic (ALC between 0.2 and 0.8 mg/L of aerosol) based on the total atmospheric concentration of aerosol and 2,4,4-trimethylpentene vapor, the ALC for the mixture was 4.1 mg/L.

Reason for Changes

This report was revised at the request of the Sponsor to reflect the correct purity and composition of the test substance. The following pages were revised to reflect this change: the original report will be maintained in the Medical Research file at Haskell Laboratory.

Page 1 Title page
Page 2 General Information
Page 3 General Information (cont'd)
Page 4 Summary/Signature
Page 5 Quality Assurance Documentation
Page 8 Records Retention
Page 10 Discussion and Conclusion

Additional Page

Page 11 Reason for Revision No. 1

DuPont HLR 256-88
Revised Page

Revised by:

John W. Sarver

John W. Sarver
Toxicologist

5/1/97

Date

R. Valentine

Rudolph Valentine
Study Director
Inhalation & Cellular Toxicology

5/1/97

Date